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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/536,485 | 05/24/2005 | Giovanni Meazza | 163-626 | 6851 |
| 47888 | 7590 | 02/23/2009 | EXAMINER | |
| HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 | | | MURRAY, JEFFREY H | |
| ART UNIT | PAPER NUMBER | | | |
| | | | 1624 | |
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| 02/23/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/536,485 | Applicant(s) MEAZZA ET AL. |
| | Examiner JEFFREY H. MURRAY | Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 November 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2 and 25-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1,2,25 and 28-30 is/are allowed.

6) Claim(s) 26 and 27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1, 2 and 25-30 are pending in this application. Claims 4-25 have been withdrawn. Claim 3 has been cancelled. This action is in response to the applicants' request for a continued examination filed on November 13, 2008.

Withdrawn Rejections/Objections

2. Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Claim Rejections - 35 USC § 112, 1st paragraph

3. Claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound or composition, does not reasonably provide enablement for a compound or composition and "...other herbicides, fungicides, insecticides, acaricides and fertilizers." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte*

Forman 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

1) *Amount of guidance provided by Applicant.* While the Applicant has demonstrated within the application how to make uracils, applicant has provided no guidance, or provided any chemical or biological data and/or testing results of these particular compositions in combination with "...other herbicides, fungicides, insecticides, acaricides and fertilizers."

The quantity of experimentation needed to make or use the invention must be considered to determine if undue experimentation is present. Here applicants do not describe in any explicit detail what amounts of further active compounds have been combined with the compounds and whether they have an additive effect.

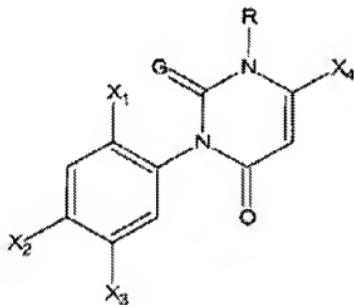
2) *Unpredictability in the art.* It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. (USPQ 18, 24 (CCPA 1970). See *In re Fisher*, 427 F.2d 833, 839, 166.

Applicants have provided no biological testing of any results where the compositions were combined with these additional "active compounds." Without this, one cannot simply *infer* that the results of the combination would be additive from the compositions or the active compounds alone. In many instances, the systematic screening of combinations of small molecules can reveal unexpected interactions between the pathways on which they act. (Borisy, et. al., Proceedings of the National Academy of Sciences of the United States of America, 100(13) 7977-7982.)

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3) *Number of working examples.* The compound core depicted with specific substituents represent a narrow subgenus for which applicant has provided sufficient guidance to make and use; however, this disclosure is not sufficient to allow extrapolation of the limited examples of compounds to enable the scope of the compositions combined with additional medicament active ingredients. Applicant has provided no working examples of any compounds which have been combined with additional medicament active ingredients in the present application.

4) *Scope of the claims.* The scope of the claims involves all of the tens of thousands of compounds and compositions of the following formula:



whereby G is O or S; X₂ is a halogen; X₄ is a haloalkyl; X₁ is a hydrogen or halogen; and is combined with "...other herbicides, fungicides, insecticides, acaricides and fertilizers" thus the scope of the claims is broad.

5) *Nature of the invention.* The present invention relates generally to uracils having a high herbicidal activity, the process for their preparation and methods for their use as herbicides for controlling weeds in agricultural crops.

6) *Level of skill in the art.* The artisan using Applicants invention would be a doctor with a M.D. degree, and having several years of professional experience. MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for treating the disease mentioned.

Allowable Subject Matter

4. Claim 1, 2, 25, and 28-30 are free of the prior art. The closest prior art to the current claim is Wanger, et. al., EP Patent No. 0255047, which teaches the same compound core modified with a methylthiazole ether group directly connected in the 3-position of the phenyl ring. The current application only permits alkyl ethers where the heterocyclic ring is an oxadiazole or a thiadiazole.

Conclusion

5. Claims 26 and 27 are rejected.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H. Murray/
Patent Examiner
Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

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